December 17, 2021

Arthrex Inc.
Rebecca Homan
Team Lead, Regulatory Affairs
1370 Creekside Boulevard
Naples, Florida 34108-5553

Re: K213644
Trade/Device Name: Arthrex Knotless Mini TightRopes
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HTN
Dated: November 16, 2021
Received: November 18, 2021

Dear Rebecca Homan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Christopher Ferreira -S

for

Limin Sun, Ph.D.
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213644

Device Name
Arthrex Knotless Mini TightRopes

Indications for Use *(Describe)*
The Arthrex Knotless Mini TightRopes are intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct to external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

Specifically, the Arthrex Knotless Mini TightRopes are intended to provide fixation during the healing process following:

1) Syndesmotic trauma, such as fixation of dorsal distal radioulnar ligament (DRUL) disruptions;
2) Tarasometatarsal (TMT) injury, such as fixation of foot soft tissue separations due to a Lisfranc injury (Midfoot Reconstruction); and
3) Hallux Valgus reconstruction (correction) by providing for the reduction of 1st metatarsal -2nd metatarsal intermetatarsal angle.

The Arthrex Knotless Mini TightRopes, when used for fixation of bone-to-bone or soft-tissue-to-bone, are intended as fixation posts, distribution bridges, or for distributing suture tension over areas of ligament or tendon repair.

Specifically, the Arthrex Knotless Mini TightRopes are indicated for Carpal Metacarpal (CMC) joint arthroplasty as an adjunct in the healing process of the thumb metacarpal by providing stabilization between the base of the first and second metacarpal when the trapezium has been excised due to osteoarthritis. The Arthrex Knotless Mini TightRopes are also indicated for use as adjuncts in the suspension of the thumb metacarpal during the healing process of hematoma distraction arthroplasty by providing stabilization at the base of the first and second metacarpal when the trapezium has been excised due to osteoarthritis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Date Prepared	December 16, 2021
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Rebecca R. Homan Team Lead, Regulatory Affairs 1-239-643-5553, ext. 73429 rebecca.homan@arthrex.com
Name of Device	Arthrex Knotless Mini TightRopes
Common Name	Button/Suture
Product Code	HTN
Classification Name	21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class	II
Primary Predicate Device	K133275: Arthrex Mini TightRopes
Predicate Devices	K061925: Arthrex Mini TightRope Repair Kit K090107: Arthrex Mini TightRope
Reference Devices	K122374: Arthrex Suture (UHMWPE) K181513: Arthrex PushLock Tenodesis Anchor K201522: Arthrex Syndesmosis TightRope XP Buttress Plate Implant System K212146: Arthrex LoopLoc Knotless Suture
Purpose of Submission	This Special 510(k) premarket notification is submitted to obtain clearance for the Arthrex Knotless Mini TightRopes.
Device Description	The Arthrex Knotless Mini TightRopes are suture and button constructs that consist of two buttons, one or more suture strands and various ancillary instruments to aid in insertion. The buttons are manufactured from titanium alloy conforming to ASTM F136 (Ti-6AL-4V ELI). The sutures are manufactured from UHMWPE, polyester and/or nylon. The devices are sold sterile and are single-use.
Indications for Use	The Arthrex Knotless Mini TightRopes are intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct to external and intramedullary fixation systems involving plates and rods, with fracture braces and casting. Specifically, the Arthrex Knotless Mini TightRopes are intended to provide fixation during the healing process following: 1) Syndesmotic trauma, such as fixation of dorsal distal radioulnar ligament (DRUL) disruptions; 2) Tarasometatarsal (TMT) injury, such as fixation of foot soft tissue separations due to a Lisfranc injury (Midfoot Reconstruction); and 3) Hallux Valgus reconstruction (correction) by providing for the reduction of 1st metatarsal -2nd metatarsal intermetatarsal angle. The Arthrex Knotless Mini TightRopes, when used for fixation of bone-to-bone or soft-tissue-to-bone, are intended as fixation posts, distribution bridges, or for distributing suture tension over areas of ligament or tendon

	repair. Specifically, the Arthrex Knotless Mini TightRopes are indicated for Carpal Metacarpal (CMC) joint arthroplasty as an adjunct in the healing process of the thumb metacarpal by providing stabilization between the base of the first and second metacarpal when the trapezium has been excised due to osteoarthritis. The Arthrex Knotless Mini TightRopes are also indicated for use as adjuncts in the suspension of the thumb metacarpal during the healing process of hematoma distraction arthroplasty by providing stabilization at the base of the first and second metacarpal when the trapezium has been excised due to osteoarthritis.
Performance Data	Ultimate Static Tensile, Ultimate Static Shear and Cyclic Fatigue testing was conducted to demonstrate that the Arthrex Knotless Mini TightRopes perform statistically equivalent to the predicate devices cleared under K133275 and K061925. MRI force, torque, and image artifact testing were conducted in accordance with FDA guidance *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*, ASTM F2052 *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*, ASTM F2119 *Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants*, ASTM F2182 *Standard Test Method for Measurement of Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging* and ASTM F2213 *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment*. Bacterial Endotoxins Test (BET) was performed on the Arthrex Knotless Mini TightRopes utilizing the Kinetic Chromogenic Method in accordance with ANSI/AAMI ST72:2011/(R)2016, USP <161>, USP <85>, EP 2.6.14. The testing conducted demonstrates that the Arthrex Knotless Mini TightRopes meet pyrogen limit specifications. Cytotoxicity, Sensitization, Irritation, Genotoxicity, Systemic Toxicity, Subchronic/Subacute Toxicity, Implantation and Material Characterization testing was conducted on the Arthrex Knotless Mini TightRopes in accordance with ISO 10993-1:2018. Assessment of physical product attributes including product, design, size, and materials as well as the conditions of manufacture and packaging has determined that the Arthrex Knotless Mini TightRopes do not introduce additional risks or concerns regarding sterilization and shelf-life.
Technological Comparison	The Arthrex Knotless Mini TightRopes are substantially equivalent to the predicate devices cleared under K133275 in which the intended use, fundamental scientific technology, sterility, shelf life, basic design features and configuration are identical. The buttons within the Arthrex Knotless Mini TightRopes will be manufactured from Titanium conforming to ASTM F136 (Ti-6AL-4V ELI); whereas the buttons within the predicate devices cleared under K133275 are

	manufactured from Stainless Steel conforming to ASTM F138. In addition to the 4-Hole Round and 2-Hole Oblong buttons, the Arthrex Knotless Mini TightRopes contain Slotted Oblong and Dual-Fixation buttons; whereas the buttons within the predicate devices cleared under K133275 contain the 4-Hole Round and 2-Hole Oblong buttons. The suture within the proposed Arthrex Knotless Mini TightRopes will be manufactured from UHMWPE, Polyester and/or Nylon; whereas the suture within the predicate devices cleared under K133275 are manufactured from UHMWPE and Polyester. The Arthrex Knotless Mini TightRopes will be packaging in a double Tyvek blister configuration; whereas the predicate devices cleared under K133275 are packaged in a double Tyvek/poly pouch configuration. The Arthrex Knotless Mini TightRopes have been evaluated for MR Conditional labeling; whereas the predicate devices cleared under K133275 were not evaluated for MR Conditional labeling. The Arthrex Knotless Mini TightRopes are a line extension to the predicate devices, which include minor dimensional modifications with no change to intended use or function. Any differences between the Arthrex Knotless Mini TightRopes and the predicate devices are considered minor and do not raise different questions of safety or effectiveness.
Conclusion	The Arthrex Knotless Mini TightRopes are substantially equivalent to the predicate device in which the basic design features and intended uses are the same. Any differences between the proposed device and the predicate device are considered minor and do not raise different questions concerning safety or effectiveness. The submitted mechanical testing data demonstrates that the ultimate tensile strength, ultimate shear strength and cyclic fatigue of the Arthrex Knotless Mini TightRopes is substantially equivalent to that of the predicate device for the desired indications. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex Inc. has determined that the proposed device is substantially equivalent to the currently marketed predicate device.